

Amendments to the Drawings:

The attached sheet of drawings includes new Figure 11, which was originally filed as Figure 14 in the application, and subsequently deleted in a Preliminary Amendment filed January 16, 2004.

Attachment: New Sheet, Figure 11

REMARKS/ARGUMENTS

Claims 1-20 are pending in the application: of which, claims 7, 13-14, and 18-20 are withdrawn from consideration; and claims 1-6, 8-12, and 15-17 now stand finally rejected by the Examiner. By way of the present amendment, claim 4 has been cancelled and claims 6, 10, 11 and 15 amended herein. Accordingly, claims 1-3, 5-6, 8-12 and 15-17 are under consideration. Support for the amendments to claims 10 and 11 can be found for example at paragraphs 17, 282 and 337 of the published application. Support for the amendments to claims 6 and 15 can be found for example at paragraph 7 of the published application.

Specification and Drawings

The specification is objected to for referring to Figures 11-20, which were deleted in an amendment dated January 16, 2004. By virtue of this response, Applicants have re-introduced original Figure 14 as new Figure 11, and have re-introduced the paragraph describing original Figure 14 (now Figure 11) that was part of the originally-filed specification. Accordingly, no new matter has been introduced by these amendments. At the Examiner's request, Applicants have also deleted references to original Figures 11-13 and 15-20 from the specification.

Claim Objections

Claims 4 is objected to, as being of improper dependent form for failing to further limit the subject matter of a previous claim. In response, Applicants have canceled claim 4.

Claims 6 and 15 are objected to for the use of the acronym "CLASP-2," without first defining what they represent in the independent claims. Applicants have amended claims 6 and 15 accordingly.

Claim Rejections - 35 USC §101 and §112, first paragraph

Claims 1-6, 8-12, and 15-17 are rejected under 35 USC 101 because the claimed invention is not supported by either a credible, specific, and substantial asserted utility or a well established utility. The claims are further rejected under 35 USC §112, first paragraph, on the grounds that one skilled in the art would not know how to use the claimed invention since it allegedly lacks utility.

More specifically, the Office Action states that "Although the specification . . . teaches that CLASP-2 expression levels decrease at 1 hour, 2 hours, and 4 hours after T cell activation (pg 125, lines 4-14), it cannot be determined if this decrease is a significant decrease as compared to T-cells that have not been activated. . . . Applicant is encouraged to submit an evidence under 37 CFR 1.132 that would indicate a significant difference between the expression of CLASP-2 in activated and inactivated T cells." Office Action, at page 7.

In response, Applicants have re-introduced original Figure 14 (now renumbered as Figure 11) into the application; this Figure was originally present in the specification as filed but was subsequently deleted. Original Figure 14 (now Figure 11) sets forth the results showing that CLASP-2 expression was decreased upon T-cell activation (also described in Example 9).

As explained by Dr. Peter S. Lu in the attached declaration, this Figure indicates the presence of multiple inbuilt controls that establish the significance of the decrease in CLASP-2 expression, as follows:

- 1) As explained in the specification (Example 9, page 124, lines 4-8), each mRNA sample taken at 0 and subsequent hours after T-cell activation was adjusted to ensure that equal amounts of total RNA were loaded onto the gel. In addition, "[e]ven gel loading was monitored by ethidium bromide staining" of the gel (paragraph 482 of the published application). The uniform, even intensities of the 28S rRNA bands at 0, 1, 2 and 4 hours post activation in original Figure 14A (now re-introduced as Figure 11A) confirm that the decrease in CLASP-2 expression was specific for CLASP-2 alone, and did not occur for other mRNAs in general.

- 2) The first sample taken at 0 hours post activation indicates the level of CLASP-2 mRNA in unactivated T cells - this level is higher than CLASP-2 levels and 1 and 2 hours post-activation.

In addition, Dr. Peter S. Lu in his attached declaration submits data (Exhibit 2) showing the expression of a similar but distinct gene (CLASP-1) at 0, 1, 2 and 4 hours post-activation. As seen, levels of CLASP-1 mRNA did not show a decrease and 1 and 2 hours post activation. In fact, the levels were seen to increase slightly instead. As Dr. Peter S. Lu explains, this data confirms that the decreased expression of CLASP-2 is significant and specific to CLASP-2 alone.

Accordingly, CLASP-2 has a specific and substantial utility. Applicants request this rejection be withdrawn.

Claim Rejections - 35 USC §112, first paragraph

Even if the claimed invention is eventually deemed to have utility, the Office Action notes that claims 10-12 would remain rejected for lack of enablement because these claims allegedly encompass transgenic animals, the production of which is unpredictable.

In response, Applicants have amended claims 10 and 11 to specify that the host cell is an isolated cell or a prokaryotic cell or a yeast cell. Applicants request the rejection be withdrawn.

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Examining Group 1647

PATENT

If the Examiner believes a telephone conference would expedite prosecution of this application, please telephone the undersigned at 650-326-2400.

Respectfully submitted,



Ashita A. Doshi
Reg. No. 57,327

TOWNSEND and TOWNSEND and CREW LLP
Two Embarcadero Center, Eighth Floor
San Francisco, California 94111-3834
Tel: 650-326-2400
Fax: 415-576-0300
Attachments
AAD:llm
61206000 v2